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K102179

CareFusion EnView™ Camera Controller
510(k) Summary

DEC - 2 2010

Submitter: CareFusion
6215 Ferris Square, Suite 100
San Diego, CA 92121

Contact Person: Patricia Ayers
Regulatory Affairs

Date Prepared: July 30, 2010

Trade Name: EnView™

Common Name: Camera controller

Classification: 78 OCV, Endoscope Holder and Accessories
21 CFR §876.1500

Class: II

Predicate Devices: V.Mueller Camera Controller with Storage Cart, K093616
Prosurgics Freehand, K090340

Intended Use: The EnView™ camera controller is intended for use by surgeons and their designees to hold rigid endoscopes with diameters from 5 - 10mm during diagnostic and therapeutic surgical procedures.

A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, hernia repair, fundoplication, splenectomy, appendectomy, hemicolectomy, sympathectomy, lymph node dissection, hysterectomy, gastric banding, gastric bypass, nephrectomy, radical prostatectomy.

Device Description: The EnView™ camera controller is a manually operated mechanical surgical device. It is designed to hold an endoscope during diagnostic and therapeutic surgical procedures. A surgeon can, with one hand, position and

reposition the placement of an endoscope during a surgical procedure by simple movements of a control handle. This camera controller eliminates the need for the surgeon to continually hold the endoscope during a surgical procedure.

Substantial Equivalence:

The EnView™ camera controller is substantially equivalent in operation, design, materials, and manufacturing characteristics as the V.Mueller Camera Controller and Storage Cart, and is substantially equivalent with respect to indications for use as the Prosurgics Freehand.

Non-Clinical Testing:

Testing was performed under various conditions to assess the design performance and conformance to design specifications. In addition, the EnView™ camera controller met ISO 10993:2003 and ISO 17664:2004 standards. As with the V.Mueller Camera Controller, IEC 60601 testing was not required for the EnView camera controller due to the mechanical and hydraulic mode of operation.

Clinical Testing:

Clinical studies were not required as the EnView™ camera controller is substantially equivalent to the legally marketed predicate devices with respect to operation and indications for use.

Safety and Efficacy:

The EnView™ camera controller is equivalent in safety and efficacy to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CareFusion
% Ms. Patricia Ayers
6215 Ferris Square, Suite 100
San Diego, California 92121

DEC - 2 2010

Re: K102179
Trade/Device Name: EnView™ camera controller
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCV
Dated: October 12, 2010
Received: October 14, 2010

Dear Ms. Ayers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): Pending K102179

DEC - 2 2010

Device Name: EnView™ camera controller

Indications for Use: The EnView™ camera controller is intended for use by surgeons and their designees to hold rigid endoscopes with diameters from 5 - 10mm during diagnostic and therapeutic surgical procedures.

A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, hernia repair, fundoplication, splenectomy, appendectomy, hemicolectomy, sympathectomy, lymph node dissection, hysterectomy, gastric banding, gastric bypass, nephrectomy, radical prostatectomy.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102179

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